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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,343	10/11/2000	Pierre Chameau	03495.0197	4371

22852 7590 12/15/2004

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EXAMINER

ANGELL, JON E

ART UNIT PAPER NUMBER

1635

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/685,343

### Applicant(s)

CHARNEAU ET AL.

### Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 53-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-55 and 58-79 is/are rejected.
- 7) ☒ Claim(s) 56 and 57 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/24/04 has been entered. Claims 53-79 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 53-55 and 58-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Zufferey et al. (Nature Biotech. 1997 cited in IDS filed as Paper No. 4).

Zufferey teaches an isolated/purified nucleic acid comprising retroviral  $\Psi$  packaging sequences, cis-acting nucleic acid sequences for reverse transcription and virus integration, a cis-

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acting RRE, a pol gene which comprises at least one cPPT sequence and at least one CTS sequence and the intervening pol sequences, and a heterologous nucleic acid sequence of interest; as well as methods of using said nucleic acid for delivering the nucleic acid sequence to the nucleus of a target cell for expressing a gene of interest encoded by the heterologous nucleic acid sequence.

Specifically, Zufferey teaches, an HIV-1 based vector “in which the expression cassette for the transgene is flanked by the HIV-1-derived cis-acting sequences necessary for packaging, reverse transcription and integration” (see p. 871, last paragraph). Zufferey indicates that the transgene of the vector can be a reporter gene, such as Luciferase or lacZ (e.g., see p. 873, Table 1, Table 2). Zufferey teaches methods of using the vector to deliver the transgene into cells where it is expressed (indicating delivery to the nucleus) as well as assays which encompass isolating the reporter gene and assaying for its presence/activity (e.g., see Tables 1, 2). It is noted, as set forth in a previous Office Action, that HIV-1 based vectors were known to infect non-dividing cells as well as HeLa cells and hematopoietic stem cells.

Regarding claims 53-55, 58-74 and 76-79, it is noted that claims 53-55 and 58-74 are drawn to isolated/purified nucleic acid sequences comprising retroviral sequences consisting of at least one cPPT sequence and at least one CTS sequence and the intervening pol sequences. This claim encompasses any isolated/purified nucleic acid sequence comprising a retroviral sequence having at least one cPPT and CTS sequence and the intervening pol sequences. The instant claims are not limited to nucleic acid sequences that comprises a cPPT sequence, a CTS sequence and the intervening pol sequence **wherein the vector DOES NOT COMPRISE ANY OTHER pol SEQUENCES OTHER THAN THE cPPT, CTS and INTERVENING pol**

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**SEQUENCES.** It is noted that a nucleic acid comprising retroviral nucleic acid sequences consisting of particular sequences does not limit the claim to a nucleic acid comprising only the indicated retroviral nucleic acid sequences. This is because of the recitation “an isolated or purified nucleic acid **comprising**” in the preamble of the claims. “Comprising” is considered open language, and as such, the instant claim must have the indicated retroviral nucleic acid sequences and may have other sequences as well. Therefore, a nucleic acid sequence comprising retroviral sequences consisting of at least one cPPT sequence and at least one CTS sequence and the intervening pol sequences may also comprise other retroviral pol sequences. The vector taught by Zufferey includes a pol sequence that includes a cPPT and CTS sequence and the intervening pol sequences, as well as other pol sequences (and the other claimed retroviral sequences). Therefore Zufferey clearly anticipates the instant claims. Furthermore, claims 76-79 are drawn to an isolated or purified nucleic acid comprising retroviral nucleic acid sequences **comprising** the indicated sequences. These claims are clearly not limited to isolated/purified nucleic acid sequences that comprises a cPPT sequence, a CTS sequence and the intervening pol sequence wherein the isolated/purified nucleic acid sequence **DOES NOT COMPRISE ANY OTHER pol SEQUENCES.** Therefore, Zufferey clearly anticipates these claims as well.

Regarding claim 75, the claim is drawn to a nucleic acid comprising the *ClaI* insert or the *EcoRI/BamHI* or both the *ClaI* insert AND the *EcoRI/BamHI* insert of pTRIPΔU3EF1αGFP. It is noted that the claim encompasses any nucleic acid encoding ANY these inserts. Based on the disclosure in the specification it appears that the CLAI insert comprises triplex forming nuclei acid sequence which has the cPPT and CTS sequences. Since the claim encompasses any nucleic acid sequence comprising the *ClaI* insert, Zufferey, which teaches a HIV-1 based vector

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comprising the pol sequence that comprises cPPT and CTS sequences (e.g., see Fig. 3, p. 873), anticipates the instant claim.

It is noted that limiting the claims to the vector that is pTRIPΔU3EF1αGFP and methods of using this vector for delivering a nucleic acid of interest to cells in vitro and expressing the transgene in cells in vitro would be free of the prior art.

### ***Claim Objections***

Claim 56-57 objected to because of the following informalities: it appears that claim 56 comprises a grammatical error that is considered a typographical error. Specifically, the claim recites, "A vector pTRIP...". It is believed that the claim is intended to recite "A vector that is pTRIP...". Claim 57 is objected to because it depends on claim 56. Amending claim 56 as indicated would obviate this objection. Appropriate correction is required.

### ***Response to Arguments***

Applicant's arguments filed 8/24/04, have been fully considered. With respect to the previously indicated rejections under 35 USC 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraph, the arguments (in view of the amendment) is persuasive. Therefore, said rejections have been withdrawn.

With respect to the rejection of claim 75 under 35 USC 102(b) applicants argue:

"[T]he claimed nucleic acid includes an EF1α promoter, which is not disclosed by Zufferey et al. In fact, the Office explained that Zufferey et al. disclose a CMV promoter in Figure 3 on page 873. In contrast, the specification describes that an EcoRI/BamHI fragment was used to replace the CMV promoter present in the precursor plasmid with an EF1α promoter. See specification at page 32, lines 15-18. The EF1α promoter is, therefore, part of the TRIP ΔU3 EF1α GFP plasmid from which the claimed nucleic acid is derived." (See p. 11 of the response filed 8/24/04).

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Applicants' arguments are persuasive to the rejection as it pertains to the previously filed claims. However, the instant claims have been amended such that the nucleic acid is no longer limited to a nucleic acid sequence comprising the ClaI insert and the EcoRI/BamHI insert of pTRIPΔU3EF1αGFP. Rather, the instant claims encompass a nucleic acid sequence comprising the ClaI insert OR the EcoRI/BamHI insert or both ClaI and EcoRI/BamHI inserts of pTRIPΔU3EF1αGFP. Since the claim has been amended as indicated, Applicants arguments are not persuasive with respect to the instant rejection based on the teachings of Zufferey.

Furthermore, since the claims have been amended a new grounds of rejection (based on the teachings of Zufferey) have been set forth for the reasons indicated herein.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.  
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DAVE T. NGUYEN  
PRIMARY EXAMINER